

REMARKS

Claims 24-25, 27-34, 38-42, 51-55, 59-61, 67-68, 71-77, 83-108 are pending.
Claims 67 and 73 are amended.

Claim 67 is amended to add a missing "of."

Claim 73 is amended to correct the spelling of "sulfate."

Entry of this Amendment and the accompanying terminal disclaimers, and reconsideration of the claims, as amended, is requested.

The Section 112 Rejection

Claims 83, 84, 88 and 89 are rejected under 35 USC § 112, second paragraph, as being indefinite. Specifically, the PTO questions how the claimed compositions with the stated components can have the claimed pH. This rejection is traversed.

The foregoing claims are directed to liquid pharmaceutical compositions comprising a minimum of certain components, namely, an erythropoietin glycoprotein, sodium sulfate and arginine, and having a particular pH (from about 6 to about 6.5). As the claims contain the term "comprising," it is not legally required that the pH range be achieved with just the enumerated components. On the contrary, the claimed compositions may include other components, for example as is shown in the Examples. The pH range is a required parameter of the claims, it is not necessarily a direct result of just the specifically-enumerated components of the compositions of the claims.

By questioning the stated pH range, the PTO is in effect requiring that the applicant include yet another component in the claimed pharmaceutical composition. There is no basis on the current record for such a requirement. As applicant uses "comprising" in these claims, this rejection is legally improper and factually incorrect and should be withdrawn.

The Obviousness Type Double Patenting Rejections

Claims 67-68, 71, 73, 75, 77, 83, 85, 86, 91-101 and 104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of US Pat. No. 6,583,272 (Bailon). This rejection is overcome.

Generally, the instant application is directed to a liquid pharmaceutical compositions comprising and erythropoietin glycoprotein, a multiple charged inorganic anion and a buffer and having specific pH. In contrast, the Bailon '272 patent claims erythropoietin conjugates.

Applicant repeats and relies upon his previous arguments that this rejection is legally improper. In particular applicant reiterates the argument presented in the Amendment dated June 7, 2005 that there is no legal basis for the PTO's position that a pharmaceutical composition claim that requires specific components is necessarily obvious, and thus requires a terminal disclaimer over, a prior compound patent that does not claim any pharmaceutical composition at all.

While applicant adamantly believes that this rejection is legally incorrect, the instant application is directed to an important product that is in phase III clinical trials and as such applicant wishes to avoid any more delays in the prosecution of this application. Consequently, applicant submits herewith a terminal disclaimer of the instant application over the '272 Bailon patent. The double patenting rejection over the '272 Bailon patent is thus overcome.

Analogously, claims 67-68, 71-77 and 91-108 are also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of co-pending USSN 10/014,363 (CD 20805). This rejection is traversed.

For the same reasons offered with respect to the '272 patent, this rejection is also legally improper. Applicant reiterates the arguments already of record that claims 1-15 of the '363 application are directed to an erythropoietin conjugate and as such cannot be deemed improperly to "overlap" with the instant composition-specific claims. In addition, while claim 16 of the '363 application is directed to a pharmaceutical composition, it does not describe or suggest the specific components and pH of the compositions of the instantly pending claims. As such, it also does not "overlap" with the instant application.

Furthermore, claims 1-16 of the '363 application currently stand rejected. Applicant does not know which claims, if any, of the '363 ultimately may be allowed or what their scope will be. As such, it is premature to lodge this rejection *in the instant application*. Applicant thus requests that the double patenting rejection over the '363 application be withdrawn as being legally improper or, in the alternative, be held in abeyance until there is an indication of which claims in each application are allowable, at which point the merits of the rejection more properly can be assessed.

Additionally, claims 24, 25, 27-34, 38-42, 51-55, 59-61, 67, 68, 71-77 and 83-108 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over allowed claims 1-16, 18, 22-37 and 39-68 of co-pending application USSN 10/780,297 (20619 US1), which is a child application of the instant application. This rejection is overcome.

For the reasons already of record, applicant again maintains that this rejection is also legally improper. However, due to the significance of the instant application and applicant's desire to expedite prosecution, applicant is submitting herewith a terminal disclaimer over USSN 10/780,297 (20619 US1). The double patenting rejection over USSN 10/780,297 is thus overcome.

The Section 102(e) Rejection

Claims 67-68, 71, 73, 75, 77, 83, 85, 86, 91-101 and 104 are rejected under 35 USC § 102 (e) as being anticipated by Bailon US Pat. No. 6,583,272 B1 (Bailon). This rejection is again traversed.

This rejection was lodged previously (albeit against differently numbered claims) and in response thereto applicant submitted the Declaration of Dr. Appollon Papadimitriou under 37 CFR 1.132. Dr. Papadimitriou is the sole inventor of the instant application. In his February 5, 2004 Declaration, Dr. Papadimitriou averred that he is the sole inventor of formulations A-I presented in Example 8, Table 3, of the Bailon '272 patent. In the Office Action dated May 12, 2004, the Patent Office accepted Dr. Papadimitriou's Declaration and withdrew the Section 102 (e) rejection. See, Office Action of May 12, 2004, page 3, paragraph 6. In the recent Office Action dated August 1, 2005, the Section 102 (e) rejection is reinstated because the "Declaration of Dr. Appollon Papadimitriou filed under 37 CFR 1.132 is not suitable for the withdrawal of the 102(e) rejection, since Dr. Appollon Papadimitriou is not an inventor of U.S. Patent 6,583,272." See Office Action of August 1, 2005, page 12. The Patent Office's dismissal of the Papadimitriou Declaration is unfounded. Thus, the rejection under Section 102 (e) is legally improper and should be withdrawn.

MPEP Section 715.01 provides that a Rule 132 Declaration may indeed be used to overcome a Section 102(e) rejection "by proving that the subject matter relied upon in the reference or activity was applicant's own invention." Moreover, in Section 716.10, entitled "Attribution," an analogous fact pattern to that presented here is discussed. Section 716.10 provides that an earlier filed application (in this case the Bailon patent) containing a disclosure that is not claimed and having an inventive entity that is different from a subsequently filed application claiming the earlier disclosed but not claimed subject matter is available as a reference against the subsequently filed application unless it is overcome by a Rule 131 declaration showing prior invention or a Rule 132

declaration stating the named inventor of the subsequent application “conceived or invented the subject matter disclosed in the [earlier] patent or published application. Disclaimer by the other patentee or other applicant of the published application should not be required but if submitted, may be accepted by the Examiner.” MPEP § 716.10, pp. 700-249 to 250 (2/2/03 Rev., *emphasis added*).

There is no reason on the current record for the PTO not to accept the Declaration of Dr. Papadimitriou. As such, the PTO’s statement that the Declaration is “unsuitable” is unsupported and improper. The MPEP specifically provides for use of such a declaration in the factual situation herein presented. The Papadimitriou Declaration should once again be accepted and the Section 102(e) rejection withdrawn.

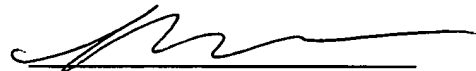
CONCLUSION

Applicant submits this Amendment, and the accompanying terminal disclaimers, are fully responsive to all of the issues raised in the Office Action issued August 1, 2005, and that all pending claims are allowable. Early and favorable consideration is earnestly solicited.

If the Examiner believes there are other issues that can be resolved by telephone interview, or that there are any informalities remaining in the application which may be corrected by Examiner’s Amendment, a telephone call to the undersigned attorney is respectfully solicited.

Applicants believe that no fee is due with this communication. However, should the Patent Office determine that a fee is owed, or a credit is due to applicant, the Patent Office is hereby authorized to charge any required fees, including any extension of time and/or excess claim fees, or credit any overpayment, to applicant's Deposit Account 08-2525 as appropriate.

Respectfully submitted,



Attorney for Applicant(s)
Patricia S. Rocha-Tramaloni
(Reg. No. 31,054)
340 Kingsland Street
Nutley, New Jersey 07110
Telephone: (973) 235-2441
Telefax: (973) 235-2363

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